UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WARSAW ORTHOPEDIC, INC., Plaintiff, v. NUVASIVE, INC., Defendant.	Case No.: 12-CV-2738-CAB-MDD **ORDER GRANTING MOTION FOR SUMMARY JUDGMENT** [Doc. Nos. 207, 214, 218]

Before the Court is defendant NuVasive's motion for summary judgment of non-infringement of U.S. Patent No. 5,676,146 ("the '146 patent"). [Doc. Nos. 218, 247-1.][1] Plaintiffs (collectively "Warsaw") opposed. [Doc. No. 236.] NuVasive submitted a reply [Doc. No. 250-1], and the Court held oral argument. Having considered the submissions of the parties and the arguments of counsel, the motion is **GRANTED**.[2]

[1] All page references to docket entries correspond to the CM/ECF assigned page numbers for the docketed material.

[2] In light of the Court's finding of non-infringement of the asserted claims, the Court declines to reach the defendant's alternative arguments regarding improper claim broadening and invalidity, as well as its motion on damages. [Doc. No. 214.] These motions are deemed moot. In addition, the pending motions seeking to exclude the opinions of experts [Doc. Nos. 207, 214] are denied.

I. The Patented Invention and the Accused Product

The invention of the '146 patent is directed to a surgical implant containing a resorbable radiopaque marker and a method of locating the implant within a body. [Doc. No. 1-2.] The implant, which can be used to repair skeletal defects and irregularities, incorporates radiopaque material, e.g., nondemineralized or partially demineralized bone particles, which is resorbable in its entirety and may contribute to the healing of bone through natural processes. [Id., at Col. 1:30-40.] This radiopaque material is distributed in radiolucent resorbable or non-resorbable material, during the manufacture of the implant such that the radiopaque material serves as a marker, which can be visualized by x-ray or other radiographic technique, facilitating the determination of the location and/or position of the implant within a body. [*Id.*, at Col. 1:44-48; Col. 3:4-10.]

NuVasive makes and sells a product called Osteocel Plus, an allograft bone matrix. [Doc. No. 247-2.] Osteocel Plus is used for the repair, replacement or reconstruction of musculoskeletal defects in a variety of surgical and implant applications. Warsaw accuses this product of direct infringement, and also alleges that NuVasive's sale and instruction regarding the use of this product as a surgical implant constitutes indirect infringement.

The components of Osteocel Plus include cancellous bone chips, demineralized bone, and mesenchymal stem cells and osteoprogenitor cells. NuVasive promotes this product as a complete "cocktail" for various musculoskeletal applications to support fusion due to its inclusion of these three components necessary for bone healing; cells (the mesenchymal stem cells and osteoprogenitor cells), signals (the demineralized bone) and scaffold (the cancellous bone chips). [*Id.*, at 3.] Osteocel Plus is packaged by placing the cancellous bone particles which include the cells in a jar, adding the demineralized bone to the jar and then mixing them with a cryopreservation solution for frozen storage. [Doc. No. 247-6.]

NuVasive contends that the evidence Warsaw relies upon to support its allegations of infringement does not demonstrate that Osteocel Plus meets the limitations of the

asserted claims. NuVasive therefore moves for a judgment of non-infringement as a matter of law.

II. Legal Standard

Under Federal Rule of Civil Procedure 56(a), "the court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The moving party has the burden of establishing the absence of a genuine dispute of material fact. The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Matsushita Elec. Inds. Co. Ltd., v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial. *Id.*

After an adequate time for discovery, a motion for summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (holding that the moving party is entitled to a judgment as a matter of law if the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof).

Determining whether a patent claim is infringed requires a two-step inquiry: first, the claim must be properly construed to determine its scope and meaning; second, the claim as properly construed must be compared to the accused device or method. *See Wolverine World Wide, Inc., v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994). The party alleging infringement bears the burden of proving by a preponderance of evidence that every

limitation set forth in the asserted claim is found in accused product or process, either literally or by substantial equivalent. *Id.*[3]

III. The Asserted Claims

Warsaw alleges NuVasive's Osteocel Plus product infringes the following claims of the '146 patent [Doc. No. 1-2.].

> 13. A method of determining the location and/or orientation of an osteogenic surgical implant within a body which comprises:
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> a) surgically implanting within a body an osteogenic implant fabricated from a radiolucent material comprising allograft bone particles and an radiopaque material comprising particles of nondemineralized or partially nondemineralized allograft bone, the radiopaque material being uniformly distributed within the radiolucent material, wherein the radiopaque material is provided in sufficient quantity for use as a marker; and
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> b) post-surgically determining the location and/or orientation of the implant by a radiographic technique.
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> 15. The method of claim 13 wherein the radiographic technique is x-ray imaging.
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> 21. An osteogenic surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material including demineralized allograft bone particles in substantially uniform admixture with a radiopaque material including particles of nondemineralized or partially demineralized allograft bone, wherein the radiopaque material is provided in sufficient quantity for use as a marker.
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> 25. An osteogenic surgical implant for surgical implantation in the body comprising nondemineralized or partially demineralized allograft bone particles and demineralized allograft bone particles uniformly distributed in an inert carrier, the nondemineralized or partially demineralized allograft bone particles being provided in sufficient quantities for use as a marker, the surgical implant being stored in a package for subsequent implantation.

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[3] In its opposition to NuVasive's motion, Warsaw withdrew its allegations of infringement by the doctrine of equivalence [Doc. No. 236, at 13], so the analysis herein is limited to sufficiency of Warsaw's evidence of literal infringement of the claims at issue.

> 26. An osteogenic surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material in substantially uniform admixture with particles of nondemineralized or partially demineralized bone, wherein the particles of nondemineralized or partially demineralized bone are provided in sufficient quantities for use as a radiopaque marker, the surgical implant being stored in a package for subsequent implantation.

Each of the asserted independent claims is directed at a surgical implant that includes in its composition radiopaque material (nondemineralized or partially nondemineralized allograft bone) which is uniformly distributed throughout or in a substantially uniform admixture with radiolucent material, in sufficient quantity for the radiopaque material to act as a marker for the determination of the location and/or orientation of the implant after surgical implantation in the body.

IV. Claim Construction and Reexamination Proceedings

The parties submitted certain terms and phrases for claim construction, including the phrase *uniformly distributed within*. However, they withdrew their request for construction of *uniformly distributed,* sought only the construction of the word *within.* Although the plain meaning of *within* would ordinarily be "inside," in the context of the patent disclosure the Court found such a construction to be nonsensical. It is clear from the specification that the radiopaque material is uniformly distributed throughout the radiolucent material comprising the implant. The patent does not teach putting the radiopaque material inside the radiolucent material; such a construction would be illogical. Consequently, to the extent the word *within* results in any ambiguity the Court construed it to mean in this context, throughout. [Doc. No. 143.]

The invention of this patent is directed at fabricating an otherwise radiolucent surgical implant with sufficient radiopaque material distributed throughout it, such that the implant can be readily visualized by x-ray or other radiographic technique following implantation in the body. The Court also found that individuals of skill in the art will understand that the limitation that the particles of nondemineralized or partially demineralized bone be *provided in sufficient quantity for use as a marker* means the

quantity of radiopaque material used in the implant must be adequate to allow for the ready visualization by x-ray or other radiographic technique of the implant after implantation. *Id.*

Following the issuance of the Court's claim construction order, NuVasive filed a request for ex parte reexamination by the Patent Office of the '146 patent. [Doc. No. 229-6, at 2-17.][4] All the asserted claims were subject to NuVasive's request for reexamination contending the claims were unpatentable under 35 U.S.C. §103. The examiner instituted the reexamination and initially rejected the asserted claims in light of the prior art submitted by NuVasive. [*Id.* at 62.]

In response to the prior art presented in the reexamination, Warsaw submitted argument and declarations from experts with regard to the meaning and scope of the claim terms *uniformly distributed* and *substantially uniform admixture* and the claim limitation that the particles of nondemineralized or partially demineralized bone be *provided in sufficient quantity for use as a marker*. Specifically, Dr. Barton Sachs stated, on behalf of the patent owner, that to distinguish over prior art references, art that disclosed making a composite graft of demineralized and non-demineralized bone and the taking of post-surgical x-rays is not sufficient to demonstrate that the radiopaque material functioned as a marker as required by the claims. "[T]here are several variables that are required for the cancellous tissue to have been able to function as a marker, including the distribution and positioning of the radiopaque material, the ratio and volumes of radiopaque and radiolucent material, the components selected, and the size and processing of component. The processing of product is key." [Id., at 79-80.]

Dr. Sachs explained that it is difficult to evenly mix particles of different sizes and densities to achieve the substantially uniform admixture or a uniform distribution as described in the patent, and particularly impractical in an operating room environment. [*Id.* at 76, 93-94.] According to Dr. Sachs, "[a] uniform composite graft instead would need to

[4] The Court denied NuVasive's request to stay this litigation while the claims were in reexamination, so the Patent Office proceeding and the District Court litigation continued as parallel proceedings for a while.

be created in a tissue processing lab using measured quantities of materials, which are consistent, following a reproducible, predictable processing procedure." [*Id.* at 76.]

Dr. Sachs further represented that there is a fundamental distinction between having an individual component that is radiopaque and having the radiopaque portion function as a marker for the entire graft. The reason, he explained, that the asserted claims required a uniform distribution of the radiopaque material in the graft or that the graft be a substantially uniform admixture is to ensure that the graft as a whole is readily visible in a radiograph. [*Id.* at 186.] "Unless the radiopaque material is properly mixed and there is a sufficient quantity of the material, the material itself could be radiopaque, but would not serve as a marker for the implant as a whole. … The radiopaque material must be uniformly distributed and/or be a substantially uniform admixture.…" [*Id.* at 185.] If, for example, the radiopaque material is concentrated to one side it would be difficult to locate or orient the implant post-implantation. He emphasized to the patent examiner that prior art did not disclose the proper volume and size of the radiopaque material, the correct ratio to the radiolucent material, and the uniform distribution of the radiopaque material throughout the whole of the composite graft, all of which are needed for the radiopaque material to act as a marker for the determination of the location and/or orientation of the surgical implant. [*Id.* at 186.]

Based on the patent owner arguments, including Dr. Sachs' declaration, the patent examiner reversed his earlier rejection of the claims. [*Id.* at 236-241.] Confirming the asserted claims over the prior art, the examiner concluded that the prior art did not teach radiopaque material being uniformly distributed within or in substantially uniform admixture with the radiolucent materials. The examiner adopted the patent owner's explanation that to function as a marker, as claimed in the patent, a sufficient quantity of radiopaque material must be uniformly distributed, one type of particle relative to the other type of particle, in an arrangement throughout the implant. Disclosures that taught mixing alone of the particles did not sufficiently disclose this limitation. [*Id.* at 239-240.]

Prosecution history is an important part of the intrinsic record relevant to claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). Statements made by Warsaw in the reexamination proceeding are relevant to the interpretation of key terms. *See e.g.*, *Evolutionary Intelligence, LLC v. Sprint Nextel Corp.*, No. C-13-03587, 2014 WL 4802426, at *4 (N.D. Cal. Sept. 26, 2014) ("Statements made by [the patent holder] during the IPR could disclaim claim scope, aid the court in understanding the meaning of the terms, or otherwise affect the interpretation of key terms."). In light of the patent holder's representations, made and adopted in the reexamination proceeding to distinguish over prior art, this Court construes the claim limitation that the radiopaque material be *uniformly distributed within* or in *substantially uniform admixture* with the radiolucent material as requiring more than the two components being mixed together. To be *uniformly distributed within* or in *substantially uniform admixture*, the component particles must be arranged consistently one type of particle relative to the other type of particle throughout the combination.

The patent owner further represented that this uniformity of distribution of the radiopaque material relative to the radiolucent material in the implant is important to establish the marker limitation. While some quantity of radiopaque material in the implant may provide visualization by x-ray or other radiographic technique after implantation, visualization alone does not necessarily meet the marker limitation. To act as a marker, i.e., provide for the determination of the location and/or orientation of the surgical implant, the radiopaque material must also be uniformly distributed throughout the entire implant to provide for visualization of the whole implant, not just a portion of it. The phrase *provided in sufficient quantity for use as a marker* is therefore further defined to mean the quantity of radiopaque material used in the implant must be adequate to allow for the ready visualization by x-ray or other radiographic technique of the implant **as a whole** after implantation.

V. Infringement Analysis

With fact and expert discovery now closed, Warsaw must demonstrate that the accused product meets the uniform distribution or substantially uniform admixture claim limitation. To that end, the evidentiary support for Warsaw's contention that NuVasive's Osteocel Plus product infringes the claims of the '146 patent is set forth in the expert report of Julie Glowacki, Ph.D. [Doc. No. 247-10.] Dr. Glowacki opines that the radiopaque component in Osteocel Plus is uniformly distributed or in substantially uniform admixture with the radiolucent component based on her review of Osteocel Plus marketing materials and its processing protocol. [*Id.* ¶¶76-81.] Dr. Glowacki's conclusion is based on the following evidence identified in her report [*Id.* ¶¶76-82]:

> 1) Osteocel Plus is marketed as a "complete 'cocktail'" with viable stem cells "well integrated within the matrix." [Doc. No. 247-2, at 3; Doc. No. 247-23, at 44.] Further, a NuVasive witness testified that surgeons are instructed to use the whole product as both components in the product, the demineralized material and cancellous material, are important. [Doc. No. 247-7, at 35.]
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> 2) During processing the product is "shake[n] vigorously to mix." [Doc. No. 247-4, at 15.] Further NuVasive represented its development team was "working towards packing and formulation improvements which may help ensure a consistent, homogenous product." [Doc. No. 247-24, at 3.]
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> 3) Surgeons are informed that "once thawed Osteocel Plus will settle to the bottom of the container." They are instructed when filling an implant cage with the product or packing a disc space, to deliver Osteocel Plus using a spatula and to "scoop product from the jar rather than pick up individual pieces to assure delivery of homogenous mixture." [Doc. No. 247-2, at 3.]

After reviewing this evidence, the Court finds that none of it actually supports Dr. Glowacki's conclusion.

A. The Description of Osteocel Plus as a Complete Solution Does Not Support the Conclusion the Product Meets the Claim Limitation.

It is undisputed that the Osteocel Plus matrix is comprised of demineralized bone matrix ("DBM") and cancellous bone chips (non-demineralized bone particles) which

contain human stem cells. NuVasive markets this combination as a "complete cocktail" because it provides all three components necessary for bone repair. [Doc. No. 247-2, at 3.] The cancellous bone chips are processed to retain viable stem cells within the chips, the stem cells thereby being well integrated within the matrix. [Doc. No. 247-23, at 44; 247-3, at 9-11.] These representations by NuVasive, that Osteocel Plus is a medically complete solution, however do not support Dr. Glowacki's conclusion that the combination of these components in the mixture necessarily meets the limitation of uniform distribution or substantially uniform admixture to provide a marker.

Warsaw itself has argued the contrary conclusion with regard to prior art practices. According to Warsaw's expert Dr. Sachs, creating composite implant that maximizes biological activity is in "contra-distinction" to creating a composite implant that meets the limitation of uniform distribution or substantially uniform admixture needed for the cancellous material to act as a marker for the entire implant. [Doc. 229-6, ¶20.] Dr. Sachs states that a matrix that includes the elements necessary for bone repair does not necessarily have the desired level of uniformity required by the patent. "To achieve the maximum benefits associated with each of the components of the composite graft, having a substantially uniform admixture or a uniform distribution of the materials is not necessary. . . . [T]he materials must simply be brought together, ensuring that all of the DBM, for example, is not in a single place. . . . [H]aving a substantially uniform admixture or a uniform distribution of the materials in the graft, generally, is not medically beneficial." [Doc. No. 247-11, at 20-21.]

NuVasive's marketing statements regarding the medical benefits of the accused composite product are not sufficient evidence from which one can conclude that Osteocel Plus meets the claim limitation of uniform distribution or substantially uniform admixture. The fact the components are present in combination, as Dr. Sachs notes, does not demonstrate that they are necessarily present in uniform distribution throughout the implant. Nor do the materials Dr. Glowacki relies upon, which speak to the medical benefits of the combined components, make any mention that the cancellous material is or

should be distributed uniformly relative to the DBM throughout the whole implant so it can act as marker to determine the location and/or placement of the implant.

B. The Packaging Protocol for Osteocel Plus Does Not Support the Conclusion the Product Meets the Claim Limitation.

The protocol for the packaging of Osteocel Plus instructs that the nondemineralized cancellous bone is measured and placed in a jar, the DBM is measured and placed on top, and then a cryoprotectant solution is added to cover both bone products. The jar is covered and vigorously shaken to mix, and visually inspected to ensure that all bone product is submerged in the cryoprotectant solution. [Doc. No. 247-4, at 8-16.] Based on this protocol, Dr. Glowacki concludes that this processing step results in a product that meets the limitation of uniform distribution or substantially uniform admixture.

Dr. Glowacki contends that this shaking step is performed to ensure "proper mixing" of all the components." [Doc. No. 427-10, ¶78.] By "proper mixing," she infers that the shaking step is intended to and results in a uniform distribution or substantially uniform admixture of the bone products within the jar. The protocol however makes no reference to achieving a proper mix of the two bone components in a consistent particle to particle arrangement in the jar. Nor does it disclose any inspection or testing steps to confirm such a result.

This processing step of "vigorous shaking" is performed after the cryoprotectant solution is added. The jar is capped and shaken to ensure all the bone product is submerged in the solution before freezing. [Doc. No. 247-4, at 15-16.] Frank Vizesi, Ph.D., NuVasive's Manager of Research and Development for Biologics, testified that "the vigorous shaking step is to ensure the cryoprotectant is fully engaged with the particles, with the -- with the cancellous bone and the DBM." [Doc. No. 247-7, at 35.]

What constitutes "vigorous" and how long the technician should shake the jar is not set forth in the processing protocol. The specific implementation of this mixing step is left to the discretion of the individual technician governed only by the visual assessment that the bone products are fully submerged in the cryoprotectant solution as a result. The step

set forth in the protocol does not comport with Dr. Sachs's requirement that the processing procedure be a reproducible, predicable processing protocol because it is "key" to achieving the uniform composite graft claimed in the invention. [Doc. No. 229-6, at 76, 79-80 (a uniform composite graft needs to be created in a tissue processing lab using measured quantities of materials, which are consistent, following a reproducible, predictable processing procedure).]

Dr. Glowacki provides no factual support for her conclusion that this processing step -- vigorous shaking, for an unspecified amount of time -- actually results in the DBM and cancellous bone mixing into a uniform distribution or substantially uniform admixture throughout the jar. She has not replicated the process, performed any tests, or referred to any publications or other authority that this protocol results in a mixture sufficient to meet the claim limitation, requiring a consistent particle to particle arrangement throughout the composition. Thus, the ultimate conclusion in her report does not create a genuine factual dispute sufficient to defeat summary judgment. *Applied Companies v. U.S.*, 144 F.3d 1470, 1475 (Fed. Cir. 1998) (an affidavit alone in the absence of evidentiary support, is insufficient to create a genuine issue of material fact).

Moreover, Dr. Sachs on behalf of Warsaw, when discussing prior art, contends that mixing by hand generally does not satisfy this limitation. Although the component parts will combine by this shaking step, the two component particles of different size and density are "difficult to mix evenly," into a substantially uniform admixture or uniform distribution, according to Dr. Sachs. [Doc. No. 247-11, ¶58.] For example, he notes that "demineralized bone powder commonly sticks to itself and clumps when it comes in contact with fluid." [*Id.* ¶84.]

A substantially uniform admixture or uniform distribution, according to Dr. Sachs and consistent with Warsaw's representations in the reexamination proceeding, means that "the components are positioned in a certain manner within the composite, relative to one another, in a uniform spacing." He opined that even a product described as a "very, very, very well mixed" composition does not specify the relative position of the components to

each other in the mixture. [Doc. No. 247-13, at 40-42.] Dr. Sachs analogizes it to a salad with slices of grilled chicken that is shaken up or mixed in a bowl. The whole composite is combined, while the slices of grilled chicken may not be uniformly distributed within the salad. [*Id.* ¶65.]

With regard to the protocol in this case, the shaking distributes the cryoprotectant solution (the salad dressing, to continue the analogy) among the component bone particles, but it is an assumption without foundation that the DBM, initially layered above the cancellous bone component in the jar, and the cancellous bone will end up distributed evenly and consistently relative to each other throughout the jar after fluid is added and the jar is shaken. The NuVasive documentation, referenced by Dr. Glowacki, indicating that NuVasive continues to work toward packing and formulation improvements which may help ensure a consistent, homogenous product, further supports a conclusion that the protocol does not, in fact, result in a consistent, uniform distribution. [Doc. No. 247-24, at 3 (emphasis added).]

C. The Implant Preparation Guide for Osteocel Plus Does Not Support the Conclusion the Product Meets the Claim Limitation

The processing protocol evidences that the cancellous bone particles with stem cells and the DBM are present in combination submerged in the cryoprotectant solution when Osteocel Plus is frozen. There is no evidence that this composition in the cryoprotectant solution is in uniform distribution, or a substantially uniform admixture. Nor is there any evidence that this composition would remain in uniform distribution suspended in this liquid composite prior to freezing, even if the shaking step momentarily achieved such a result.

To prepare for use as an implant, the surgical user is directed to thaw the jar containing the product in a warm sterile bath "until the material in the vial flows freely upon inversion." [Doc. No. 247-6, at 2.] The guide states that once thawed "Osteocel Plus will settle to the bottom of the container." Using a screen to retain the graft material in the jar, the user is instructed to decant the cryopreservation solution from the jar, and then

cover the material with warm sterile saline until the user is ready to pack the implant cage or disc space. The sterile saline is then decanted. Using a spatula, the user is directed to "scoop product from the jar rather than pick up individual pieces to assure delivery of homogenous mixture." [Id., at 2-3.]

Dr. Glowacki concludes from this preparation guide that the combination of the component bone materials is and remains in uniform distribution, or a substantially uniform admixture, throughout these steps. She bases this on the statement that the product settles to the bottom of the container, from which she assumes the product's component particles when they settle are and remain positioned in a uniform spacing relative to one another in the composite. There is no evidence, however, to support a conclusion that the bone materials in the jar, after being inverted in a free flowing state, will retain any uniformity of arrangement, particle to particle relative to each other.

This conclusory assumption is without foundation and is contradicted by Dr. Vizesi, who testified that the component parts of the product, both of which are important medically, are not uniformly distributed. [Doc. No. 247-7, at 35.] He explained that the implantation preparation guide specifically directs the surgeons to scoop the product from the jar, because the DBM portion settles to the bottom, and if the surgeon picks out larger cancellous pieces from the top, he will not get the benefit of the entire product. Consequently, the surgeons are instructed to scoop out the product so they do not leave behind an important component of the product, the DBM at the bottom of the jar. [Id.]

If the components were in uniform distribution throughout the jar, as assumed by Dr. Glowacki, a surgeon packing the material into the implant cage or disc space, could take product from the top of the jar and be confident he would get both the components in consistent, uniform quantity relative to each other. The bone products however, separate in solution, as explained by Dr. Vizesi, such that one product can be picked out from the top of the jar resulting in the other being left behind. This instruction to scoop the product from the jar does not support Dr. Glowacki's assumption the bone components are uniformly distributed in the jar.

VI. Conclusion: Warsaw Has Not Made a Sufficient Showing on an Essential Element of Its Case.

The patent holder bears the burden of proving by a preponderance of evidence that every limitation set forth in the asserted claim is found in accused product. *Wolverine World Wide, Inc.*, 38 F.3d at 1196. Moreover, in satisfying this burden accuser is limited to the construction of the claims that it advocated in the IPR review. "Claims may not be construed one way in order to obtain their allowance and in a different was against accused infringers." *Southwall Tech. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

Here, as discussed above, the sole evidence Warsaw offers to support its infringement claims is an expert report that is based on a construction of the claims that is inconsistent with the construction argued by Warsaw through Dr. Sachs and adopted by the Patent Office in the reexamination proceeding to overcome prior art. "To be *uniformly distributed within* or in *substantially uniform admixture*, the component particles must be arranged consistently one type of particle relative to the other type of particle throughout the combination." Distinguishing over prior art, Dr. Sachs argued that mixing alone does not meet this limitation, "even a very, very, very well mixed composition does not specify the relative position of the components to each other in the mixture." There is no evidence that "vigorously shaken," while perhaps resulting in a well-mixed composition, results in a composition in which the component particles are arranged particle to particle consistently throughout the composition as required by the claim term.

Dr. Glowacki's conclusory opinion that it does, standing alone, does not create a material fact in dispute. The Court finds that no reasonable jury can conclude on the evidence presented by Warsaw in opposition to NuVasive's motion for summary judgment that Osteocel Plus meets the claim limitation of *uniformly distributed within* or in

substantially uniform admixture. For this reason the motion for summary judgment of non-infringement of the asserted claims 13, 15[5], 22, 25 and 26 is **GRANTED**.

Dated: February 17, 2016

Hon. Cathy Ann Bencivengo
United States District Judge

[5] If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1545, 1553 (Fed. Cir. 1989).